

REMARKS

The Applicants respectfully request entry of this Amendment. No new matter is added by this Amendment.

Claims 1-39 are pending in the application. Claims 40-41 have been added.

Claim Rejections – 35 U.S.C. § 112

Claims 1-39 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner indicates that the claims recite detecting the risk of cardiac syndromes. The Examiner also indicates “a syndrome is usually a grouping of symptoms without a specific diagnosis. Myocardial infarction is a specific diagnosis. It seems that syndrome is not the proper word to use. As far as the scope of the claims is concerned. The examiner is relying on applicants’ definition of cardiac syndrome on page 1, i.e., myocardial infarction, non-ST-elevated MI, and cardiac ischemia.”

Applicants disagree with the rejection. As noted in the ACC/AHA Practice Guidelines entitled “Guidelines for the Management of Patients with Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction,” (referred to herein as “the Guidelines”) the “term acute coronary syndrome (“ACS”) (or acute cardiac syndrome as used in the present application) has evolved as a useful operational term to refer to any constellation of clinical symptoms that are compatible with acute myocardial ischemia. It encompasses acute myocardial infarction (ST-segment elevation and depression, Q wave and non-Q wave) as well as unstable angina.” The Guidelines, page 973. The Guidelines further discuss when ACS is diagnosed and the information needed to diagnose ACS. Accordingly, Applicants believe that the use of the term cardiac syndromes is appropriate in the claim language. Applicants respectfully request that the Examiner withdraw this rejection.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2, 5-17, 23, 25-36, 38, and 39 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,443,889 (“Groth”) in combination with U.S. Patent No. 6,059,724 (“Campell”). Claims 3-4 and 18-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Groth in view of Campell, and further in view of U.S. Patent No. 6,394,952 (“Anderson”) and U.S. Patent No. 6,142,078 (“Lachajewski”).

To establish a *prima facie* case of obviousness under Section 103, three basic criteria must be met. *M.P.E.P.* § 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art, to modify the references or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior-art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. *See M.P.E.P. § 2143.1.* Moreover, it is improper to combine references where the references teach away from their combination. *See M.P.E.P. § 2145.* The Office's proposed combination of references does **not** meet the above criteria with respect to the subject matter of the claims.

Independent Claim 1 calls for a method of diagnosing cardiac syndromes, the method comprising the acts of acquiring data from a first diagnostic test; processing the data from the first diagnostic test to produce an indicator; acquiring data from a second diagnostic test; processing the data from the second diagnostic test to produce a second indicator; combining the indicators; and calculating a risk of a cardiac syndrome based on the combination of indicators.

Groth does not teach or suggest, among other things, the act of calculating a risk of a cardiac syndrome based on the combination of indicators. *See Office action dated October 6, 2003, pages 2-3.* Campell does not cure the deficiencies of Groth. Campell does not teach or suggest, among other things, the act of calculating a risk of a cardiac syndrome based on the combination of indicators. In addition, there is no suggestion or motivation to combine the references.

The Office indicates that the combination of Groth and Campell disclose the subject matter of Claim 1, and that it would have been obvious to modify Groth based on the teachings of Campell. *See Office action dated October 6, 2003, pages 2-3.*

Groth discloses a system and method of providing decision support for early assessment of patients with suspected acute myocardial infarction ("AMI"). The system utilizes a trained and tuned artificial neural network uses patient specific parameters 40, which are acquired from the patient shortly after entering a medical care facility, and AMI variables 42 to calculate decision regions 32, 52 (e.g., non-AMI, minor AMI, medium AMI, major AMI). Col. 5, line 61-col. 6, lines 65; Figs. 8a-8c. The AMI variables are used to determine which decision region 32, 52 the patient should be referred to at a specific point in time. Col. 5, lines 44-52. A second set of data can be acquired at a subsequent time and input into the system to determine which decision region 32, 52 the patient should be referred to at the subsequent time. Col. 11, line 63-col 12, line23. In other words, the system is used

to determine whether the patient suffered an AMI and the severity of the AMI to determine management and treatment options. Col. 12, lines 28-35.

Campell discloses a system for predicting the future health of an individual. The system acquires biomarker data for an individual and predicts an individual's future health based on statistically comparing the individual's set of biomarker values with a longitudinally-obtained database of sets of a large number of individual biomarker values for a large test population. Col. 6, lines 12-32. Biomarker data can be acquired over an individual's lifetime. Col. 6, lines 33-51. The system provides a quantitative estimate of the probability of an individual acquiring a specified biological condition within a specified period of time. Col. 6, lines 52-55.

There is no suggestion or motivation to combine the teachings of Groth and Campell because each system is using different data for analysis and making very different conclusions. The system in Groth is using artificial neural networks to determine, based on AMI-related data if a patient has experienced an AMI and what level of damage has occurred to determine management and treatment options. In contrast, the system in Campell acquires biomarker data over any length of time to provide a probability of an individual acquiring a biological condition within a certain period of time when compared to other individual biomarker data. One system (Groth) uses present data to determine a past condition or event. The other system (Campell) uses present and past data of one individual to determine the probability of a future event when compared to data from other individuals.

For at least these reasons, Groth and Campell do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 1 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 1 is allowable. Dependent Claims 2-17 depend from Claim 1, and are therefore allowable for the same and other reasons.

Independent Claim 18 calls for a cardiac syndrome diagnostic system comprising a first cardiac activity acquisition device operable to generate a first cardiac activity data; a second cardiac activity acquisition device operable to generate a second cardiac activity data; one or more processors to generate a first and second indicator based on the first and second cardiac activity data, respectively; and a fusion engine operable to receive the first and second indicators, generate a first and second set of degrees of membership based on the first and second indicators, and generate a risk of a cardiac syndrome based on a combination of the first and second sets of degrees of membership and a set of predetermined rules.

Groth does not teach or suggest, among other things, a cardiac syndrome diagnostic system including a fusion engine operable to receive the first and second indicators, generate a first and second set of degrees of membership based on the first and second indicators, and generate a risk of a cardiac syndrome based on a combination of the first and second sets of degrees of membership and a set of predetermined rules. *See Office action dated October 6, 2003*, pages 2-3. Campell, Anderson, and Lachajewski do not cure the deficiencies of Groth. Campell, Anderson, and Lachajewski do not teach or suggest, among other things, a cardiac syndrome diagnostic system including a fusion engine operable to receive the first and second indicators, generate a first and second set of degrees of membership based on the first and second indicators, and generate a risk of a cardiac syndrome based on a combination of the first and second sets of degrees of membership and a set of predetermined rules. In addition, there is no suggestion or motivation to combine the references.

The Office indicates that the combination of Groth, Campell, Anderson, and Lachajewski disclose the subject matter of Claim 18, and that it would have been obvious to modify Groth based on the teachings of Campell, Anderson, and Lachajewski. *See Office action dated October 6, 2003*, pages 2-3.

Anderson discloses a system for reading test data and software for converting the data into diagnostic or risk assessment information. Col. 2, lines 27-29. The system is to be used at the point of care where a rapid and accurate result is desired. Col. 11, lines 40-45. The system can include, expert systems, fuzzy logic, non-linear regression analysis, etc. Col. 8, lines 22-31. Specifically, the system is used for diagnosing or predicting conditions such as pregnancy, including ectopic pregnancy, pre-eclampsia, preterm labor or imminent delivery and fetal membrane rupture. Col. 15, lines 16-20. A patient sample is acquired and positioned on a test strip for testing by the system. Col. 16, lines 26-59. The system outputs a disease risk index or medical diagnosis. Col. 11, lines 58-59.

Lachajewski discloses an adaptive control system for use with a printing press to control the setting of an ink control device that regulates the amount of ink applied to paper. Col. 3, lines 14-18. The system utilizes fuzzy logic, which includes the concept of fuzzy sets and membership functions. Col. 8, line 45-col. 9, line 14.

As discussed above with respect to Claim 1, there is no suggestion or motivation to combine the teachings of Groth and Campell. In addition, there is no suggestion or motivation to combine Lachajewski with Groth, Campell, and Anderson. The system in Lachajewski works with a printing press, and is in no way related to medical-related systems.

One having ordinary skill in the art would not look to printing systems to solve a problem with medical-related systems.

For at least these reasons, Groth, Campell, Anderson, and Lachajewski do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 18 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 18 is allowable. Dependent Claims 19-22 depend from Claim 18, and are therefore allowable for the same and other reasons.

Independent Claim 23 calls for a diagnostic system comprising a first physiological activity acquisition module; a second physiological activity acquisition module; and a fusion engine operable to receive data from the first and second modules and to generate a risk of ACS based on a combination of the data received from the first and second modules.

Groth and Campell do not teach or suggest, among other things, a diagnostic system including a fusion engine operable to receive data from the first and second modules and to generate a risk of ACS based on a combination of the data received from the first and second modules. In addition, there is no suggestion or motivation to combine the references. Rather than re-present the arguments set forth above with respect to this contention, for brevity's sake, Applicants refer to the discussion above for Claim 1. With respect to this claim, the same arguments apply to the lack of a suggestion in the references that the teachings of the references should or could be combined and to the contention that the references actually teach away from the combination suggested by the Examiner.

For at least these reasons, Groth and Campell do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 23 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 23 is allowable. Dependent Claims 24-36 depend from Claim 23, and are therefore allowable for the same and other reasons.

Independent Claim 37 calls for a method for diagnosing acute cardiac syndromes (“ACS”), the method comprising the acts of acquiring ECG data; processing the ECG data to produce an ECG indicator; acquiring biomarker data; processing the biomarker data to produce a biomarker indicator; combining the indicators; and calculating a risk of ACS using fuzzy logic rules.

Groth does not teach or suggest, among other things, the act of calculating a risk of ACS using fuzzy logic rules. *See Office action dated October 6, 2003, pages 2-3.* Campell

and Anderson do not cure the deficiencies of Groth. Campell and Anderson do not teach or suggest, among other things, the act of calculating a risk of ACS using fuzzy logic rules. In addition, there is no suggestion or motivation to combine the references.

The Office indicates that the combination of Groth, Campell and Anderson disclose the subject matter of Claim 37, and that it would have been obvious to modify Groth based on the teachings of Campell and Anderson. *See Office action dated October 6, 2003, page 4.*

As discussed above with respect to Claim 1, there is no suggestion or motivation to combine the teachings of Groth and Campell.

For at least these reasons, Groth, Campell, and Anderson do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 37 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 37 is allowable.

Independent Claim 38 calls for a method of diagnosing cardiac syndromes, the method comprising the acts of acquiring data from a plurality of diagnostic tests; processing the data from the plurality of diagnostic tests to produce a plurality of indicators; combining the plurality of indicators; and calculating a risk of a cardiac syndrome based on the combination of the plurality of indicators.

Groth and Campell do not teach or suggest, among other things, the act of calculating a risk of a cardiac syndrome based on the combination of the plurality of indicators. In addition, there is no suggestion or motivation to combine the references. Rather than represent the arguments set forth above with respect to this contention, for brevity's sake, Applicants refer to the discussion above for Claim 1. With respect to this claim, the same arguments apply to the lack of a suggestion in the references that the teachings of the references should or could be combined and to the contention that the references actually teach away from the combination suggested by the Examiner.

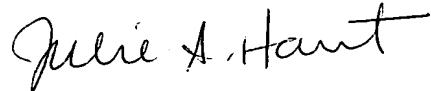
For at least these reasons, Groth and Campell do not provide the necessary motivation and suggestion to be combined. Therefore, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness of Claim 38 based upon the prior art as required by 35 U.S.C. § 103. Accordingly, independent Claim 38 is allowable. Dependent Claim 39 depends from Claim 38, and is therefore allowable for the same and other reasons.

Applicants have added new Claims 40-41, which Applicants believe are allowable over the cited art.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully request entry of this Amendment and allowance of Claims 1-41. The undersigned is available for telephone consultation at any time.

Respectfully submitted,



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